

II. Remarks

A. Status of the Claims

Claims 3-7 and 9-10 will be pending after entry of this amendment. Claims 2 and 8 have been cancelled without prejudice. Claims 1 and 11-54 were previously cancelled. Claims 4 and 10 have been amended without prejudice to correct claim dependency. Applicant submits that no new matter has been added by virtue of this amendment.

Prior to addressing the rejections, Applicant wishes to thank the Examiner for withdrawing the rejection under 35 U.S.C. §112, second paragraph, as indicated in the Office Action.

B. Claim Rejections Under 35 U.S.C. §103(a)

In the Office Action, claims 2-10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Reed et al. (WO98/16645). In making this rejection, the Examiner stated that "[g]iven that the protein sequence was known, one of ordinary skill in the art would instantly envision a polynucleotide sequence consisting of a DNA encoding said sequence and that said DNA sequence is obvious. Furthermore, it would have been obvious to one of ordinary skill in the art to place the sequence into a vector, transform a host cell with that vector, and to admix said vector with a pharmaceutically acceptable diluent or filler as taught by Reed et al. for the other DNA sequences in the document."

This rejection is respectfully traversed. Applicant submits that, in view of Reed et al., one of skill in the art would not have been motivated to create a vector, cell, or composition, comprising a DNA molecule or sequence encoding MBTN4 polypeptide, wherein the polypeptide is not encoded by the genome of the Bacille Calmette Guérini (BCG) strain of *Mycobacterium bovis*, as recited in the present claims.

Applicant respectfully submits that one of skill in the art would not be motivated to: (i) select the specific amino acid sequence described in Reed et al., i.e. SEQ ID NO:110, out of the extensive list of 209 possible sequence choices; and then (ii) incorporate a DNA sequence encoding that amino acid sequence into a vector, cell, or composition as presently claimed. In addition to the vast number of sequences listed in Reed et al., Applicant points out that SEQ ID NO:110 is mentioned only once in Reed et al., with no description of its function, use, or characteristics.

Further, Applicant respectfully submits that the situation presented by the instant application is analogous to a situation in which the prior art teaches a large genus that encompasses a claimed species. In both situations, (i) the prior art discloses a broad and generic class of components and (ii) the claimed invention somehow incorporates a single component from that class. The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. MPEP 8th Edition, 6th revision, 2144.08 II citing *In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994). In *Baird*, the Court noted that while the prior art "unquestionably encompass[ed]" the claimed invention when certain variables were selected, there was nothing in the prior art suggesting that one should select the variables that would yield such an invention. *Baird* at 382. Applicant submits that the extensive set of 209 sequences contained in Reed et al. is analogous to the genus disclosed by the prior art in *Baird*. While Reed et al. discloses the amino acid sequence for SEQ ID NO:110, there is nothing in Reed et al. to suggest that one should select that particular amino acid sequence and combine a DNA molecule encoding that amino acid sequence with additional elements to yield the vectors, cells, and compositions claimed in the instant application. Therefore, just as the Court in *Baird* concluded that the prior art did not "teach or fairly suggest" the selection of variables that would yield the invention at issue in that case, Applicant respectfully submits that Reed et al. likewise does not teach or fairly suggest the selection of a DNA sequence encoding MTBN4 for combination with additional elements to yield the vectors, cells, and compositions to yield the invention of the instant application.

Applicant respectfully submits that the invention of the present claims exploits Applicant's discovery that MTBN4 is encoded by the genome of *M. tuberculosis*, but is not encoded by the genome of the BCG strain of *M. bovis*. Reed et al. does not recognize or suggest this unique characteristic in its identification of SEQ ID NO:110. The Examiner is reminded that "it [is] important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). Therefore, Applicant submits that without the benefit of hindsight derived from the present application, one of ordinary skill in the art would not have recognized MTBN4's unique characteristics and thus would not have been motivated or prompted to combine the DNA sequence encoding MTBN4 with additional elements to achieve the vectors, cells, and compositions claimed in the instant application.

Accordingly, Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) be removed.

III. Conclusion

In view of the amendments made and arguments presented, it is believed that all claims are in condition for allowance. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is invited to telephone the undersigned at (973) 422-6532. The undersigned also may be contacted via e-mail at lschroeder@lowenstein.com. All correspondence should be directed to the address listed below.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment, to Deposit Account 50-1358.

Respectfully submitted,
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